



**NC State Health Director's Statewide Standing Order for
FDA Authorized Novavax COVID-19 Vaccine Administration
May 23, 2023**

Purpose: To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons 12 years of age and older who meet the criteria established by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) and to administer Novavax COVID-19 vaccine to persons who meet criteria set-forth by the Food and Drug Administration in accordance with FDA [Emergency Use Authorization](#).

Note: On September 8, 2022, CDC/ACIP revised their recommendation on COVID-19 booster vaccines which expanded access to the COVID-19 updated, bivalent booster to include those who are 12 years of age and older and have completed the primary series of Novavax.

On October 19, 2022, The FDA and CDC revised their recommendation regarding use of NOVAVAX as a booster dose. Now under EUA, those 18 years and older may receive NOVAVAX as a booster under limited circumstances. (See age-appropriate standing order for this age group). Children 12-17 who completed the NOVAVAX primary series are eligible to receive any of the authorized age-appropriate bivalent boosters.

NOTICE: On January 26, 2023, the FDA revised the EUA for EVUSHELD and rescinded authorization for use in the United States until further notice by the agency. EVUSHELD is no longer effective against the most prevalent circulating strains of SARS CoV2. Therefore, any recommendations for use as a therapeutic for COVID-19 have been removed from this standing order.

Note: As of May 19, 2023, CDC is no longer accepting enrollment into the v-safe program. Any mention of v-safe has been removed from this standing order.

Policy: This standing order authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina [Session Law 2022-74, Sec. 9G.7.\(a\)-\(e\)](#) or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively "vaccinators") to administer COVID-19 Vaccines authorized by the FDA per conditions of this order.

COVID-19 Vaccination	
	An up-to-date vaccination schedule for primary, additional and booster doses of authorized COVID-19 Vaccines for 6 months and older is available here .
Situation: Patients presenting for vaccination	<p>Patients 12 years or older and who present requesting vaccination with Novavax COVID-19 vaccine, adjuvanted, will receive:</p> <p>Primary Series:</p> <ol style="list-style-type: none">1. A two-dose primary series (0.5 mL each)<ol style="list-style-type: none">a. given at least 3 weeks apart for persons who are NOT immunocompromised.b. given at 3 weeks for those who self-attest that they ARE moderately to severely immunocompromised.2. An extended interval between doses 1 and 2 may be appropriate for some individuals. See table below.3. The same vaccine product should be used for all doses in the primary series.



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Intervals for Doses in Novavax Primary Series		
Dose 1 to Dose 2	NOT Immunocompromised	Moderately to Severely Immunocompromised
	3 – 8 weeks*	3 weeks

Considerations for extended interval between dose 1 and 2	
3-week interval*	8-week interval*
<ul style="list-style-type: none"> • People who are moderately or severely immunocompromised • People ages 65 years and older • When protection needs to be achieved sooner • High risk for severe disease • Living, working, or traveling to an area with high COVID-19 community levels 	<ul style="list-style-type: none"> • Reduced myocarditis risk in young adult males • Optimize vaccine effectiveness

Interval for Novavax Booster		
Last dose of Primary Novavax series	NOT Immunocompromised	Moderately to Severely Immunocompromised
	6 months	6 months

Heterologous or Mixed Primary Series

1. The same vaccine product should be used for all doses in the primary series. There are limited data on the safety and efficacy of a mixed primary series composed of any combination of Moderna, Novavax, and PfizerBioNTech COVID-19 vaccines.
2. A person who starts the Novavax primary series, but is unable to complete due to a contraindication, may be administered any other non-contraindicated and age appropriate COVID-19 vaccine at a minimum interval of 4 weeks (28 days). This does not need to be reported to VAERS.
3. Inadvertent administration of a mixed primary series:
 - a. The series is complete, and doses do not need to be repeated.



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	<p>b. This is a vaccine administration error that must be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted online or by completing and uploading this writable PDF.</p> <p><u>Booster Doses</u></p> <ol style="list-style-type: none"> The Novavax COVID-19 Vaccine, Adjuvanted is authorized for emergency use to provide a first booster dose to individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine. It is recommended that persons who complete a Novavax primary series receive 1 age-appropriate bivalent mRNA booster dose 2 months after completion of the Novavax series. <p><u>Coadministration with Other Vaccines</u></p> <ol style="list-style-type: none"> COVID-19 vaccines may be administered without regard to timing of other vaccines. Simultaneous administration is recommended when a patient is eligible for other vaccines at the time of Novavax vaccination if no specific contraindications exist.
Assessment Criteria	
Assessment Criteria: Primary Series	<p>Patients 12 years and older shall be vaccinated with Novavax COVID-19 Vaccine based on:</p> <ol style="list-style-type: none"> The conditions of this order. If patient is presenting for first dose of Novavax: ensure there is no history of previous COVID-19 vaccination, regardless of brand. If previous vaccination received outside the United States, consult CDC COVID-19 Vaccines for People Vaccinated Outside the United States. If patient presents having received the first dose of an authorized or approved COVID-19 vaccine but is unable to receive the same vaccine due to a contraindication, Novavax may be administered as the second primary series dose if there are no contraindications and at least 4 weeks have passed since receipt of the first dose.
Booster Dose	<p>Patients 18 years and older shall be vaccinated with a booster dose of Novavax COVID-19 Vaccine based on:</p> <ol style="list-style-type: none"> The conditions of this order. If the patient is 18 years of age or older, and it has been at least 6 months since the completion of their Novavax primary series. <p>NOTE: Novavax is NOT currently authorized as a booster dose for those less than 18 years of age.</p>
Plan of Care	
Actions	Patient Education and Data Collection:



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1. The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the Novavax COVID-19 Vaccine, Adjuvanted, to prevent COVID-19 in individuals 12 years of age and older.
2. The vaccinator shall also provide anticipatory guidance to include:
 - a. [CDC Pre-Vaccination Checklist for COVID-19 Vaccine.](#)
 - b. All patients should be made aware of the rare risk of Myocarditis, pericarditis, and anaphylaxis following administration of the Novavax COVID-19 Vaccine, Adjuvanted.
 - c. [Fact Sheet for Recipients and Caregivers Emergency Use Authorization of Novavax COVID-19 Vaccine Adjuvanted.](#)

Novavax COVID-19 Vaccination Administration Procedures

1. Follow the current [Pre-vaccination Checklist for COVID-19 Vaccination](#), and instruct patients accordingly or consult with overseeing provider, and instruct patients accordingly or consult with overseeing provider.
2. Review [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States.](#)
3. Review the [Fact Sheets for Healthcare Providers Administering Vaccine \(Vaccination Providers\) for Novavax COVID-19 Vaccine, Adjuvanted.](#)
4. Review *Precautions, Contraindications, and Criteria or Circumstances for Notifying Medical Provider* sections of this standing order **before** administering the COVID-19 vaccine.
5. Appropriate medical treatment and clinical staff able to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of COVID-19 vaccine.
6. A medical provider, defined as a physician, physician assistant, nurse practitioner, or a pharmacist authorized to order COVID-19 vaccines by the PREP Act must be accessible to provide medical supervision of the vaccination site/service, to assess and evaluate individuals who present with contraindications or precautions to vaccination, and to answer questions or address problems with carrying out this standing order. This may be telephone or virtual accessibility.
7. Consent must be obtained from the patient or the patient's legally authorized representative prior to vaccine administration per agency policy and in accordance with [G.S. 90-21.13](#).
8. Personal Protective Equipment: Before administering the COVID-19 vaccination, don appropriate personal protective equipment (PPE) per [CDC guidelines for COVID-19 vaccinations](#) to protect against the transmission of COVID-19.



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Contraindications

1. History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of Novavax COVID-19 Vaccine.
2. History of a known diagnosed allergy to a component of Novavax COVID-19 Vaccine.
3. People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccine.

Precautions

1. An allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types.
2. History of an immediate allergic reaction to any vaccine other than COVID-19 vaccine or to any injectable therapy.
3. History of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose Novavax COVID-19 Vaccine.
4. Moderate or severe acute illness, with or without fever
5. History of MIS-C or MIS-A.
6. History of myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine.
7. History of myocarditis or pericarditis prior to COVID-19 vaccination is NOT a precaution. These individuals may receive any currently authorized or approved vaccine after the episode of myocarditis or pericarditis has resolved.

Vaccine Preparation: Follow manufacturer's guidance for storing/handling and mixing vaccine. Refer to:

- a. Administer 0.5 mL Novavax COVID-19 vaccine to patients aged 12 and up.
- b. When a patient inadvertently receives an incorrect/inappropriate dose of COVID-19 vaccine, such errors must be reported to the Vaccine Adverse Event Reporting System (VAERS). [Interim Clinical Considerations, Appendix D, Vaccine Administration Errors, and Deviations](#)
- c. Reports can be submitted [online](#) or by completing and uploading this writable pdf.

Primary series	Dose	Volume, Route, Site
Dose 1 or 2	5 mcg SARS-CoV-2rS 50 mcg Matrix-M™ adjuvant:	0.5 mL IM injection Deltoid muscle
Booster	Dose	Volume, Route, Site



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Single dose	5 mcg SARS-CoV-2rS 50 mcg Matrix-M™ adjuvant	0.5 mL IM injection Deltoid muscle
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9. Timing:

- a. All recommended doses of Novavax COVID-19 vaccine shall be administered as close to the recommended interval as possible. Doses that are given up to 4 days (the "grace period") before the recommended interval are valid and should not be repeated. The 4-day grace period shall not be used to prospectively schedule or administer a COVID-19 vaccine dose earlier than recommended. (See interval tables above)
- b. **Single booster dose shall be administered at least 6 months after completion of NOVAVAX primary series in those 18 years of age and older.**

10. Administration:

- a. **Route of Administration:** Administer Novavax vaccine via intramuscular (IM) injection in the deltoid muscle of the arm to patients 12 years of age and older. If contraindications exist to using the deltoid, the anterolateral thigh also can be used.
- b. **Needle Gauge:** Changing needles between drawing up vaccine from a vial and injecting it into a patient is not necessary unless the needle has been damaged, contaminated, or if the needle used to draw up the vaccine is not the correct size for the patient based on their reported weight. Patients may self-report their weight for needle selection purposes. See needle sizing chart below:

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site*
Female or male fewer than 130 lbs.	22–25	1"	Deltoid muscle of arm
Female or male 130–152 lbs.	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs.	22–25	1-1 1/2"	Deltoid muscle of arm
Male 153–260 lbs.	22–25	1-1 1/2"	Deltoid muscle of arm
Female 200+ lbs.	22–25	1 1/2"	Deltoid muscle of arm
Male 260+ lbs.	22–25	1 1/2"	Deltoid muscle of arm

* Alternatively, the anterolateral thigh also can be used.

Multiple vaccinations: If multiple vaccinations are administered at a single visit, administer each injection in a different injection site following guidance in the [CDC Interim Clinical Considerations](#)

11. Documentation:

- a. **CVMS/NCIR:** Document vaccine record in CVMS or NCIR **within 24 hours** after vaccine administration per [system guidelines](#). If vaccine is documented in



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	<p>the EHR within 24 hours, providers have no more than 72 hours from administration to also enter data in CVMS or NCIR. Determining whether to document in CVMS versus NCIR should occur according to site protocol; it is not necessary to document in both systems.</p> <ul style="list-style-type: none"> b. Electronic Medical Record: If necessary, for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy. c. Provide vaccine recipients and/or their legal representative COVID-19 Vaccination Record Card indicating the vaccine dose number, product name/manufacturer, lot number, date of vaccination, name/location of vaccinator and clinic site.
	<p>Novavax COVID-19 Vaccination Observation and Follow Up</p> <ul style="list-style-type: none"> 1. Post-vaccination Observation: Nurses, EMS, or other individuals who are trained and supervised by clinical staff shall observe patients post-vaccination for immediate allergic reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) for the following time periods: <ul style="list-style-type: none"> a. 30 minutes: <ul style="list-style-type: none"> i. Persons with a history of an immediate allergic reaction of any severity to a non-COVID-19 vaccine ii. Persons with a history of anaphylaxis due to any cause iii. Persons with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Novavax/Johnson and Johnson viral vector vaccine should be observed for 30 minutes following Novavax vaccination). iv. Persons with an immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine or injectable therapy b. 15 minutes: All other persons 2. Anaphylaxis Management: Be prepared to manage medical emergencies by following your emergency response policies, procedures, and standing orders for any vaccine reaction, which must include appropriate equipment and medications (e.g., epinephrine, diphenhydramine) where vaccines are provided to respond to severe allergic reactions and anaphylaxis. See CDC Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination. 3. Syncope: Be prepared to manage syncope as it may occur in association with administration of injectable vaccines in adolescents. Procedures should be in place to avoid injury from fainting.



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Special Circumstances	<ol style="list-style-type: none"> Persons receiving immunosuppressive therapies: Whenever possible, COVID-19 vaccines should be administered at least 2 weeks before initiation or resumption of immunosuppressive therapies. Persons who received passive antibody therapy (convalescent plasma/monoclonal antibodies): <ol style="list-style-type: none"> COVID-19 vaccination can be given at any interval following receipt of passive antibody therapy. Persons should wait 2 weeks after COVID-19 vaccination before receiving tixagevimab/cilgavimab (EVUSHELD) for pre-exposure prophylaxis. People who received COVID-19 vaccination outside the United States: Consult the agency's ordering medical provider if a patient received vaccine not authorized or recommended in the US. Refer to Interim Clinical Considerations, Appendix B (People who received COVID-19 vaccine outside the United States) and take action/consult with medical provider as directed. Participants in clinical trials within or outside the United States <ol style="list-style-type: none"> Consult the agency's ordering medical provider if a patient received vaccination as part of a clinical trial.
Follow-up	<p>Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under BLA or EUA:</p> <ul style="list-style-type: none"> Vaccine administration errors Serious adverse events Cases of Multisystem Inflammatory Syndrome Cases of COVID-19 that result in hospitalization or death. <p>Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov external icon or by calling 1-800-822-7967.</p>
Precautions for Use of this Order	<ol style="list-style-type: none"> Persons with a history of an immediate allergic reaction to any other vaccine other than COVID-19 vaccine or to any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]). This includes people with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, even if it is unknown which component elicited the immediate allergic reaction. Persons with a contraindication to one type of a COVID-19 vaccine (e.g., mRNA-COMIRNATY/Pfizer or Moderna/SPIKEVAX) have a precaution to the other (e.g., viral vector-Novavax/Johnson and Johnson) because of potential cross-reactive hypersensitivity. These patients should be evaluated by a medical provider prior to vaccination. Patient self-reported moderate to severe acute illness. Persons with a precaution to vaccination must be counseled about the unknown risks of experiencing a severe allergic reaction and balance these risks against the benefits of vaccination.



NC DEPARTMENT OF
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HUMAN SERVICES**

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Contraindications for Use of this Order	5. Persons with a history of MIS-C or MIS-A. 1. Do not administer the Novavax COVID-19 Vaccine to individuals with a history of: a. Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the vaccine. b. Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.
Criteria or Circumstances for Notifying Medical Provider	1. Allergic reaction: Call 911, implement medical emergency protocols and immediately notify the medical provider providing clinical supervision of the vaccination site/service. 2. Patient reports a precaution for the vaccine. 3. COVID-19 Vaccination history cannot be determined or is not available. 4. Patients vaccinated with COVID-19 vaccines not authorized or approved in the US. 5. Patients vaccinated as part of a clinical trial. 6. Patient reports they are a HCT or CAR-T cell recipient. These patients may need revaccination, dependent on when the transplant or therapy occurred. 7. Notify the Medical Provider from the organization providing clinical supervision of the vaccination site/service at any time there are questions or problems with carrying out this standing order. Note: Healthcare providers or health departments in the United States can request a consultation from <u>CISA COVID vax</u> for a complex COVID-19 vaccine safety question that is (1) about an individual patient residing in the United States or vaccine safety issue and (2) not readily addressed by CDC or <u>Advisory Committee on Immunization Practices (ACIP)</u> guidelines.

Approved by:  _____
Elizabeth Cuervo Tilson, MD, MPH
NPI: 1760540421

Date Signed: 5-23-23 _____

This standing order is effective immediately and authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina [Session Law 2022-74, Sec. 9G.7.\(a\)-\(e\)](#) or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively “vaccinators”) to administer COVID-19 Vaccines authorized by the FDA per conditions of this order.